2 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	February 22, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Ivette Galmez Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5333, ext. 1263 Fax: 239/598.5508 Email: ivette.galmez@arthrex.com
Trade Name	***Arthrex Compression Plates***
Common Name	Plate, fixation, bone
Product Code -Classification Name CFR	HRS, HWC 21 CFR 888.8030: Single/multiple component metallic bone fixation appliances and accessories
Predicate Device	*K052614: Arthrex Low Profile Plate and Screw System* *K040907: Arthrex Small Fragment Plates and Screws* *K080111: Arthrex Compression Staple*
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the Arthrex Compression Plates.
Device Description and Intended Use	The ***Arthrex Compression Plates*** are a family of low profile plates available in various design configurations. The plates are made of stainless steel and are available in lengths of 20mm, 25mm and 30mm (interaxis lengths). The ***Arthrex Compression Plates*** are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.
Substantial Equivalence Summary	The ***Arthrex Compression Plates*** are substantially equivalent to the predicates Arthrex Low Profile Plates and Screws System in which the basic features and intended uses are the same. The ***Arthrex Compression Plates*** are substantially equivalent to the predicates Arthrex Low Profile Plates and Arthrex Compression Staple in which the material, technological characteristics and performance of the devices are similar.

SEP 25 2013

Substantial Equivalence Summary (continue)	Any differences between the ***Arthrex Compression Plates*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The submitted mechanical testing data demonstrated that the bending and compression distraction of the proposed devices is substantially equivalent to that of the predicate devices Arthrex Low Profile Plates and Arthrex Compression Staple. Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the ***Arthrex Compression Plates*** is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Arthrex, Incorporated
Ms. Ivette Galmez
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

Re: K130510
Trade/Device Name: Arthrex Compression Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Galmez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number (if known): K130510

Device Name: *Arthrex Compression Plates*

Indications For Use:

The ***Arthrex Compression Plates*** are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand, and wrist, such as opening wedge osteotomies of Hallux Valgus.

Prescription Use _✓_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices